K023801

# 510(k) Safety and Effectiveness Summary.

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR 807.92(a)

## Submitter Information

FEB 1 2 2003

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Contact Person: Mario Daniel

Date: 2002-10-29

| | |
|---|---|
| Trade Name: | LIFERAY PRO 1000 |
| Common Name: | Automatic Radiographic Film Processor |
| Classification Name: | Automatic Radiographic Film Processor |
| Regulation Number: | 892.1900 |
| Product Code: | IXW |

## Predicate Device

| | | |
|---|---|---|
| Protec Medizintecnick | OPTIMAX | K992818 |

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table

- ## Device Description:

Due to the precise roller transport system, both sheet and roller films can be processed. The Automatic film registration is activated immediately when a film is fed in. The transport system starts running. The film material is developed , fixed, rinsed and dried. With the easy to operate micro-processor, the processing conditions can be adjusted to suit the various film and chemical types. The developing solutions are temperature-regulated, circulated and automatically replenished. The feed with of the LifeRay PRO 1000 is 35cm, the smallest film format of the processor is 10x10cm.

- ## Intended Use:

The Automatic X-Ray Film Processor is intended to be used to process films exposed for medical purposes. The automatic and continuous process contains developing, fixing, washing and dryng of films.

- ## Summary of Substantial Equivalence Comparison:

The comparison of similarities and differences shows that the new device LifeRay PRO 1000 Automatic Radiographic Film Processor, which is intended to market and the predicate device:

1. Have the same intended use.
2. Have the same target user group.
3. Have the same technological characteristics.

There are no new questions about safety and effectiveness. The new device is a safe and effective as the predicate device.

The Automatic Radiographic Film Processor is substantially equivalent to the Protec Optimax Automatic X-Ray Film Processor.

- ## Technological Characteristics:

The photographic processing (developing) technique employed by the Automatic Radiographic Film Processor is the same as the predicate device. The film medium is mechanically transported for immersion in two chemical baths (developer and fixer), is rinsed in water, dried, and then ejected for viewing. The processors use mechanical rollers and guides for transportation, the solutions are temperature-regulated, circulated and automatically replenished, and same additional functions (anti-crystallization cycle, stand-by mode). Both are controlled by an integrated software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

S.A.I.E.P. S.r.l.
% Mr. Mario Daniel
Ferrania USA, Inc.
Ferrania Imaging Technologies
2700 East Frontage Road
WEATHERFORD OK 73096-6104

Re: K023801
Trade/Device Name: Film Processor, Life Ray Pro 1000
Regulation Number: 21 CFR 892.1900
Regulation Name: Automatic radiographic film processor
Regulatory Class: II
Product Code: 90 IXW
Dated: October 29, 2002
Received: November 14, 2002

Dear Mr. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

| | |
|---|---|
| 8xx.1xxx | (301) 594-4591 |
| 876.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4616 |
| 884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx | (301) 594-4616 |
| 892.2xxx, 3xxx, 4xxx, 5xxx | (301) 594-4654 |
| Other | (301) 594-4692 |

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indication for use.

Applicant: S.A.I.E.P. s.r.l.

510(k) Number (if known): K023801

Device Name: Automatic Radiographic Film Processor LifeRay PRO 1000.

Indication For Use: The Automatic Radiographic Film Processor is intended to be used to process films exposed for medical purposes. The automatic and continuous process contains developing, fixing, washing and drying of films.
This may be used in all general radiographic, diagnostic imaging procedures.
Typical users of this system are trained medical professionals, including but not limited to physicians, nurses, and lab technicians.

**(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).**

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Concurrence of CDRH, Office of Device Evaluation (ODE).

David A. Lepsen

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K023801

Prescription Use ✓
(Per 21 CFR 801.109)